

March 31, 2003

Chief, Standardization Branch  
Livestock and Seed Program  
AMS, USDA, Room 2603-S, Stop 0254  
1400 Independence Avenue, SW  
Washington, DC 20250-0254

**Re: Docket No. LS-02-02: United States Standards for Livestock and Meat Marketing Claims**

Dear Standardization Branch Chief:

Elanco Animal Health submits these comments to Docket Number LS-02-02: United States Standards for Livestock and Meat Marketing Claims. Elanco Animal Health is a global animal health company, based in Indianapolis, IN, with primary business in each of the major food animal species. Elanco Animal Health develops, manufactures and markets therapeutic and production related products that ensure animal health and welfare, and ultimately provide for a safe and abundant food supply.

Elanco Animal Health understands the United States Department of Agriculture's (USDA's) desire to bring uniformity to the standards for production/marketing claims on meat products marketed in the United States of America (USA) and appreciates the opportunity to comment on a proposal that has considerable impact on the food production sector and consumers. Our comments concern the misbranding of meat products by labeling that may be false and misleading and two specific claims relating to live animal production methods: (1) antibiotic claims and (2) hormone claims. Elanco Animal Health urges that all decisions and claims are made based on sound science and truly provide beneficial information to consumers as they make meat-purchasing decisions.

### **General Comment**

Elanco supports the Animal Health Institute's (AHI's) comments in reference to the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Federal Food, Drug, and Cosmetic Act in which all state that meat, poultry or food is misbranded if "its labeling is false or misleading in any particular." The Food and Drug Administration has developed guidance for the voluntary labeling of milk and milk products from cows not treated with recombinant somatotropin (rbST).<sup>1</sup> FDA recognizes that statements that lead consumers to conclude that milk from untreated cows is safer or of higher quality than milk from treated cows would be false and misleading. As a consequence, a producer that labels milk as "from cows not treated with rbST" must also include on the label information that would not lead the consumers to

conclude the rbST-free milk is healthier, more nutritious and safer than milk from rbST-treated cows. Elanco Animal Health believes that these principles have merit in the production and marketing claims proposed by Agricultural Marketing Service (AMS). Elanco Animal Health therefore recommends that AMS, FSIS and FDA coordinate their efforts in developing policies on production labeling claims. Labeling claims must not be false and/or misleading, but rather designed to enable a consumer to make an informed decision based on nutrition or safety information or a desired production practice. In addition, Elanco Animal Health recommends that USDA/AMS marketing claims must not mislead consumers to believe that a product produced by one production method is any safer or more wholesome than a product produced by an alternative production method. The primary focus of the label should be to provide clear information about the safety and nutrition of a product.

### **Specific Comment: Antibiotic Claims**

Today's consumers expect to have a choice of animal origin foods, and they expect assurances from U.S. authorities that the products are safe and accurately labeled. Unfortunately, many of these same consumers do not understand modern food animal production methods; particularly when antibiotics or other production tools are administered. In general differentiation of production practices with respect to antibiotic use practices on labels will only serve to confuse the consumer. For example, there is no definition that can accurately define the term "subtherapeutic" antibiotic. Inclusion of the term "subtherapeutic" antibiotic would be misleading because any antibiotic given at a dose has a therapeutic impact on some bacteria in the animal. The majority of consumers would thus tend to see the various antibiotic labeling issue as black and white – either an antibiotic was used during the life of the animal or it was not. Therefore, as one understands the consumer's desire to purchase meat products produced by different production methods it is critical that a claim is accurate and not misleading. Also the claim should not infer that one production method is any safer than a product produced by an alternative production method unless such is scientifically proven. In summary, the only meat products that should be permitted to be labeled as antibiotic-free are those derived from animals that have never been given an antibiotic either for growth promotion, disease prevention, disease control, disease treatment or any other purpose.

Furthermore, the term "antibiotic" should be defined. Prescott defines an antibiotic as a substance that is produced by a microorganism and at low concentrations inhibits or kills other microorganisms. The word antimicrobial has a broader definition than antibiotic and includes any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of a microorganism but causes little or no damage to the host. Antimicrobial is often used synonymously with antibiotic.<sup>2</sup> The broader antimicrobial definition can encompass quite a number of medicinal products, chemicals, and disinfectants that are commonly used in animal production. To what extent the proposed labeling would cause these products to be eliminated from use is unknown, but the negative consequences to hygiene, animal welfare and animal health could be severe. Therefore, we suggest that due to practical aspects that a narrower definition of antibiotic be used for the purpose of the United States Standards for Livestock and Meat Marketing Claims.

Currently, under the proposed labeling, ionophores would fall under the broader definition of an antimicrobial, as defined above, however they have a unique mode of action unlike other antimicrobials. Ionophores are extensively used in cattle and poultry production to control the endemic intestinal protozoa, coccidia, and are thus used for parasite control in cattle and poultry. Additionally, under the Animal Drug Availability Act, the FDA determined that for the purposes of data requirements to gain approval for combination drugs that, "... there is substantial evidence that each of the non-topical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness, except that for purposes of this clause, *antibacterial ingredient or animal drug does not include the ionophore or arsenical classes of animal drugs*". (Emphasis added.) Therefore, we propose that in defining antibiotic that USDA adopts the same position as FDA did for combination uses in that ionophores are not classified as antibiotics.

In alignment with AHI, we believe the use of the term "No detectable antibiotic residue (analyzed by 'method x') is inherently misleading. The label implies that meat products derived from animals withdrawn for 30 days beyond the minimum FDA withdrawal requirements are safer than the products derived by observing the FDA requirements. The FDA process for establishing the safety of animal drug residues is based on a highly scientific and conservative process with multiple safety factors applied. This labeling proposal undermines the authority of the stringent requirements put in place by the FDA for determining the safety of residues from antibiotics and the appropriate withdrawal times. Some antibiotics, e.g., penicillins, have tolerances that are at or below the detectable levels of practical analytical methods at the FDA approved withdrawal times; as this is shown by different metabolic depletion rates that vary by meat tissues and organs. Also, virtually all antibiotics would be well below any detectable levels at 30 days beyond the FDA approved withdrawal times. Further, a requirement of having no detectable antibiotic residues as verified by statistical sampling analysis using a science-based testing protocol would be redundant, unnecessary and therefore a waste of resources. Elanco Animal Health recommends that no consideration be given to a labeling standard where withdrawal periods contradict those approved by FDA.

**Summarizing, the only antibiotic claim that should be allowed is "No antibiotics used". And for purposes of the USDA AMS marketing claims, antibiotic does not include the ionophore or arsenical classes of animal drugs.**

### **Specific Comments: Hormone Claims**

The use of the terms "hormone," "growth promotant," "growth stimulant," and "implant" are potentially scientifically incorrect and misleading to the consumer. This would be misleading terminology as even vitamins and plants, such as corn and soybeans, can contain hormones and are a primary source of nutrition for food animals. For instance, vitamin D is a common feed additive and also classified as a hormone.<sup>3</sup> No animal is raised without naturally occurring hormones or some feedstuffs containing a hormone as defined broadly. Such broad use of terms will only lead to confusing a consumer in their meat purchase decision. As such, this terminology should not be used so widely as is proposed; each term has a very specific meaning. Scientifically, steroid hormone implants are definable, whereas all other terms will be inclusive of some key feed or nutritional ingredient and thus potentially misleading to consumers.

Additionally, any such “hormone claim” should not be allowed for use in those species that do not have hormones approved for use. Hormone claims allowed on meat for species that do not allow such use in production serve only to mislead the consumer relative to actual production methods.

**Summarizing, for purposes of this claim and standard the only term that should be allowed to be used is “No Steroid Hormone Implant Used” which is scientifically definable.**

Elanco appreciates the opportunity to provide input as we seek to provide information that is valuable to consumers and the food production industry. Elanco Animal Health’s comments overall align with those comments made by our trade association, the Animal Health Institute. It is critical that the USDA further refines the proposed standards for marketing claims and carefully considers the submitted comments so that the ultimate decisions do not mislead consumers, compromise the scientific integrity of the United States FDA regulatory process, or the trustworthiness of the USDA. However, we do recognize the importance of providing companies the opportunity to make marketing claims that provide guidance to consumers as they make their meat purchasing decisions.

Finally, Elanco Animal Health recommends that USDA/AMS focus carefully on those issues where the action being proposed as a standard has some meaning to the consumer of the product and avoids creating confusion or issues centered around superiority or safety of any production practice over another. The focus should be safe and wholesome food.

Sincerely yours,

Dennis L. Erpelding  
Manager, Government Relations, Public Affairs and Communications

References:

<sup>1</sup> Letter from Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, to Michael D. Dykes, Vice President, Monsanto Company (December 13, 2002).

<sup>2</sup> Prescott, J.F., 2000. Antimicrobial drug action and interaction. In: J.F. Prescott, J.D. Baggot, & R.D. Walker, eds., Antimicrobial Therapy in Veterinary Medicine, 3<sup>rd</sup> ed. Ames, IA: Iowa State University Press. p. 3.

<sup>3</sup> The Merck Veterinary Manual, Seventh Edition. p. 272.